LABORATORY CORPORATION OF AMERICA HOLDINGS

CORPORATE INTEGRITY AGREEMENT

RECITALS

- A. The parties to this Agreement are the United States Department of Health and Human Services ("HHS"), through the Office of Inspector General ("OIG"), and Laboratory Corporation of America Holdings ("LabCorp").
- B. LabCorp owns and operates a national system of clinical laboratories, draw stations, and patient services centers, including regional clinical laboratories throughout the continental United States.
- C. LabCorp wishes to demonstrate that it possesses the reliability, honesty, trustworthiness and high degree of business integrity expected of a participant in federally funded health care programs, and that it can be trusted to deal fairly and honestly with the Health Care Financing Administration ("HCFA") and the OIG.
- LabCorp has entered into a Settlement Agreement and Release with the D. United States to address civil claims against Roche Biomedical Laboratories, Inc. (a predecessor company to LabCorp), and against National Health Laboratories, Inc. and Allied Clinical Laboratories, Inc. (subsidiaries of LabCorp), for certain conduct allegedly implicating the False Claims Act, and for conduct described in the Preamble of that Settlement Agreement and Release, Paragraphs E through Z of the Preamble, and in the civil actions United States ex rel. Andrew A. Hendricks, M.D. v. Roche Biomedical Laboratories, Inc., 93 Civ. 5644 (JSM) (Southern District of New York) (filed August 13, 1993); United States ex rel, William St. John LaCorte, M.D. v. Roche Biomedical Laboratories, Inc., No. 2:96CV00417 (Middle District of North Carolina) (originally filed December 27, 1993, in the Eastern District of Louisiana, and transferred to the Middle District of North Carolina on May 15, 1996); United States ex rel. Mary J. Downy v. National Health Laboratories, Inc. and Roche Biomedical. Inc. (its successor) d/b/a Laboratory Corporation of America, [REDACTED], Civ. No. 96-0378 (District of New Mexico) (filed March 20, 1996); and United States ex rel. Geoffrey Zuccollo v. NHL/LabCorp of America et al., Civ. No. [unassigned] (Eastern District of Virginia) (filed January 4, 1996).
- E. LabCorp has adopted a Corporate Integrity Program with respect to its clinical laboratories, draw stations, and patient service centers nationwide. LabCorp

agrees to maintain its Corporate Integrity Program and to take other actions, as specified herein, to assure the OIG that LabCorp possesses the high degree of business honesty and integrity required of a Medicare and Medicaid supplier.

AGREEMENT

Term

1. This Corporate Integrity Agreement ("Agreement") shall be in force and effect for five (5) years (the "Term"), commencing on the date this Agreement is executed by all parties.

<u>Implementation</u>

- 2. LabCorp has implemented and agrees to maintain its Corporate Integrity Program ("CIP"), which includes the LabCorp Corporate Integrity Program Management described in paragraphs 6 through 11 below, the LabCorp Business Practices Compliance Policy, and the LabCorp Code of Business Practices/Ethics Handbook. The LabCorp Business Practices Compliance Policy, and the LabCorp Code of Business Practices/Ethics Handbook are hereby incorporated into this Agreement by reference. The terms of this Agreement are intended to complement and enhance LabCorp's CIP. LabCorp remains free to modify the CIP, as may be necessary to enhance its compliance efforts, and shall provide the OIG notice of any modifications of the CIP within thirty (30) days after they are implemented.
- 3. The purpose of this Agreement is to enable LabCorp to demonstrate its integrity and honesty as a participant in federally funded health care programs and its compliance with the Applicable Laws defined below. Within ninety (90) days of the effective date of this Agreement, unless a longer period is specifically provided elsewhere in this Agreement, LabCorp will implement and maintain the requirements specified herein, including any and all changes and/or additions to the existing LabCorp CIP, to ensure, to the extent reasonably possible, that LabCorp and each of its corporate directors, officers, medical directors, and employees, as well as any individuals engaged directly by LabCorp as independent contractors in the sale, marketing, and billing of laboratory services, and all phlebotomist and other individuals involved in the ordering of laboratory services, maintain the business integrity and honesty required of a participant-supplier in federally funded health care programs, and that LabCorp is in compliance with this Agreement and all laws and regulations governing a provider's participation in federally-funded health care programs,

including, but not limited to: Title XVIII of the Social Security Act, 42 U.S.C. Sections 1395-1395ccc (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. Sections 1396 et seq. (the Medicaid statute); the Medicare Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b); the False Claims Act, 31 U.S.C. Sections 3729 et seq. (as amended); the Program Fraud Civil Remedies Act, 31 U.S.C. Sections 3801 et seq.; the federal Anti-Kickback Act, 42 U.S.C. Sections 52 et seq.; and the Civil Monetary Penalties Law, 42 U.S.C. Sections 1320a-7a and 1320a-7b; and all applicable implementing regulations (hereafter "Applicable Laws"). The LabCorp CIP and the requirements of this Agreement will cover all LabCorp directors, officers, medical directors, employees, and those individuals engaged directly by LabCorp as independent contractors in the sale, marketing or billing of lab services and all phlebotomist and other individuals engaged by LabCorp who are involved in the ordering of laboratory services.

4. Within 180 days after the effective date of this Agreement, the Compliance Officer for LabCorp shall meet with HHS representatives to discuss implementation of this Agreement.

Program Enhancements

- 5. LabCorp acknowledges that every physician should be able to order only those clinical laboratory tests which the physician believes are medically appropriate for each individual patient. In order to reaffirm its commitment to this goal, LabCorp agrees to take the following actions within the time periods reflected below or such longer period of time as may be necessary for LabCorp, in good faith, to implement these changes. LabCorp will notify the OIG in writing upon completion of these actions. Failure to implement the following actions will constitute a material breach of this Agreement unless the OIG has been apprised of LabCorp's difficulty in implementing a particular action within the prescribed time period and the OIG is satisfied that LabCorp is making a good faith effort and taking reasonable action to implement such action promptly. Within thirty (30) days after receiving from LabCorp written notice of its difficulty in complying with the terms set forth below and the reasons therefor, the OIG shall advise LabCorp in writing as to whether and how much relief it will grant LabCorp.
 - a. Revision of Non-Customized Test Offerings and General Requisition Forms.
 - (1) Within twelve (12) months of the Execution Date of this

Agreement, LabCorp agrees to revise its noncustomized test offerings so that all such test offerings will be standard across the Company. LabCorp agrees to provide the OIG and HCFA a listing of the revised non-customized test offerings and sample requisition forms prior to implementation within the Company. LabCorp agrees that the OIG and HCFA are under no obligation to respond to or comment on the revised non-customized test offerings or requisition forms. The revised non-customized test offerings will emphasize physician choice and will encourage physicians to order only those tests which the physician believes are medically appropriate for each patient. With respect to chemistry tests, LabCorp will revise its noncustomized test offerings so that chemistry tests must be ordered separately except: (a) where the test is specifically part of a HCPCS defined automated multichannel test series (e.g., 80002-80019), (b) where the test is part of a CPT-defined "clinically relevant test grouping" such as an organ or disease panel or profile (e.g., 80050 et seq.), or (c) where the chemistry test is part of a profile which has been customized at the request of the physician.

- (2) In addition to revising its non-customized test offerings and general requisition forms as outlined in subsection (a)(1), above, LabCorp will include on <u>all</u> of its requisition forms, including those requisition forms prepared specially for physicians who request a customized profile, a printed reminder that when ordering tests for which Medicare or Medicaid reimbursement will be sought, physicians should only order tests medically necessary for the diagnosis or treatment of the patient.
- b. <u>Interim Review of Standard Chemistry Profiles</u>. Until such time as LabCorp implements its new requisition forms, as described in subparagraph 5.a.(1), above, LabCorp agrees that it will review each basic chemistry profile offering (Basic Chemistry Profile and Automated Chemistry Profile) for availability of physician choice and adequacy of disclosure. LabCorp agrees to advise the OIG and HCFA of any changes made to its standard chemistry profile offerings within thirty (30) days after implementation of any such change. The Interim Review of Standard Chemistry Profiles shall be conducted within six (6) months of the Execution Date of this Agreement. In the event that LabCorp is unable to implement its new requisition forms within the time period described in subparagraph 5.a.(1), a second Interim Review of Standard Chemistry Profiles shall be conducted within twelve (12) months of the Execution Date of this Agreement.
- c. <u>Test Utilization Data</u>. In order that the parties may determine whether any over-utilization of tests has occurred during the preceding year, LabCorp agrees to report to the OIG, on an annual basis, claims submission data by CPT or

HCPCS code for the top 30 tests performed at each of LabCorp's regional laboratory Divisions for Medicare and Medicaid beneficiaries, and, beginning with the report due March 1, 1999, a calculation of the percentage of growth, if any, of each such test during the preceding calendar year. Beginning with the report due March 1, 1999, LabCorp also will report to the OIG its overall growth in the total number of claims submitted for Medicare and Medicaid beneficiaries, if any, during the preceding calendar year. Such reports shall be due no later than March 1 of the year following the calendar year at issue, with the first such report on the top 30 tests performed at each lab due on March 1, 1998. Where the reports required above reveal that the growth in submitted claims for a particular test is significantly higher than the company's overall total growth in submitted claims, LabCorp will undertake reasonable inquiry to ascertain the cause of such disparity and within ten business days of the completion of such inquiry will disclose to the OIG and HCFA the results of such inquiry. If LabCorp determines that the disparity was caused by the use of basic chemistry profiles, LabCorp agrees to undertake any steps reasonably necessary to address the issue and will notify the OIG of the steps the company plans to take. LabCorp agrees to make the supporting documentation underlying its calculations available to the OIG upon request.

d. Notices to Clients.

- (1) <u>Pre-Revision Notice</u>. Within six (6) months of the Execution Date of this Agreement, LabCorp agrees to provide each physician client a notice that, for each chemistry profile that includes a multi-channel chemistry test (e.g., 80002 80019) offered by LabCorp, sets forth (a) the individual components of the profile, (b) the CPT codes for the profile, (c) for Medicare, the National Limitation Amount for the test components in the profile (if available), or a confirmation that the Medicaid maximum allowable reimbursement does not exceed the Medicare National Limitation Amount and (e) a description of how LabCorp will bill for each profile. LabCorp will, prior to issuance, provide a sample of such notice to the OIG and HCFA.
- (2) <u>Post-Revision Notices</u>. Once LabCorp has implemented its revised requisition forms as described in subparagraph 5.a., above, LabCorp will, on an annual basis, provide each client who has requested a customized profile with a notice that: (a) explains the Medicare and Medicaid reimbursement paid for each component of that profile, (b) encourages physicians who are ordering tests for which Medicare or Medicaid reimbursement will be sought to order only tests that are

medically necessary for each patient, (c) warns the client that using a customized profile may result in the ordering of tests for which Medicare or Medicaid will deny payment, and (d) advises the client that the HHS OIG takes the position that a physician who orders medically unnecessary tests for which Medicare or Medicaid reimbursement is claimed may be subject to civil penalties.

(3) Physician Acknowledgments. LabCorp also agrees to require a signed Physician Acknowledgment for all custom chemistry profiles set up for new clients and all new custom chemistry profiles set up for existing clients. The Physician Acknowledgment will state: (a) that when ordering tests for which Medicare or Medicaid reimbursement is sought, the physician should only order those tests which the physician believes are medically necessary for each patient, (b) that using a customized profile may result in the ordering of tests for which Medicare or Medicaid will deny payment, (c) that the physician should only order individual tests or a less inclusive profile where not all the tests in the customized profile are medically necessary for an individual patient, and (d) that HHS OIG takes the position that a physician who orders medically unnecessary tests may be subject to civil penalties. The Physician Acknowledgments shall also include an acknowledgment by the physician of his/her awareness of the profile components and the Medicare and/or Medicaid reimbursement amounts for the tests in each customized profile. LabCorp agrees to provide the OIG and HCFA a copy of the Physician Acknowledgment prior to its implementation, and to provide advance notice to the OIG and HCFA and a copy of the new form when the Physician Acknowledgment is revised.

e. Retention of Information

- (1) Requisition Forms. LabCorp Agrees to retain for the Term of this Agreement, either in original, electronic, microfilm or microfiche-type form, the requisition forms used by LabCorp during the Term of this Agreement. LabCorp agrees to make this information available for inspection by OIG or HCFA upon request.
- (2) <u>Compliance Pricing Guidelines</u>. During the term of this Agreement, LabCorp may decide to develop and establish basic compliance pricing guidelines applicable to all LabCorp patient list and monthly account list fee schedules. The fee schedule will reflect the value of each test listed in the respective regional laboratory Division marketplace, using at least three basic value components: (i) direct costs, (ii) indirect costs and (iii) minimum profitability expectations. LabCorp's compliance pricing guidelines will also include discounting guidelines applicable to: (i)

individual tests, (ii) overall accounts and (iii) profiles customized at the physician's request. LabCorp agrees to provide the OIG a copy of the compliance pricing guidelines and any relevant explanations or definitions, and subsequent changes to the compliance pricing guidelines. LabCorp agrees to retain copies of the compliance guidelines (and any subsequent changes) for the Term of this Agreement. LabCorp agrees that the OIG is under no obligation to respond or comment on the compliance pricing guidelines.

- (3) <u>Individual Prices</u>. Until such time as LabCorp may establish and implement the compliance pricing guidelines described in paragraph e.(2)., or for the Term of this Agreement, if LabCorp does not establish and implement such compliance pricing guidelines, LabCorp agrees to retain all individual prices negotiated with clients, either in original, electronic, microfilm or microfiche-type form.
- f. Standardized Billing Process. LabCorp represents that it has a national standardized billing process, using three separate computerized billing systems, by which all billing for clinical diagnostic laboratory services will occur. LabCorp agrees not to remove any of its laboratories from the national standardized billing process without notifying HHS within thirty (30) days of such removal. Nothing in this paragraph shall prevent LabCorp from implementing a new billing system to replace the national standardized billing process during the Term of this Agreement, provided, however, that LabCorp gives the OIG and HCFA sixty (60) days advance notice of LabCorp's intent to implement a new billing system and include in such notice a description of the new billing system.
- g. Sales and Marketing Personnel Training. In addition to the standard CIP training and education received by all LabCorp employees, LabCorp sales and marketing employees will annually receive additional compliance training in the areas of sales and marketing. Such training will focus on the sales activities which are prohibited by Applicable Laws (as defined in paragraph 47.c.) including, but not limited to, the offering of anything of value (remuneration) in return for the referral of business reimbursable in whole or in part by the Medicare and Medicaid programs. Each LabCorp sales and marketing employee will sign an acknowledgment that he or she (1) has received additional training specific to sales and marketing, (2) is aware that strict compliance with the LabCorp Standards of Conduct, CIP, and Applicable Laws, and, in particular, the prohibition against offering remuneration in return for referrals, is a condition of employment, and (3) is aware that LabCorp will take appropriate disciplinary action up to and including termination, for violation of the principles and practices set forth in the Standards of Conduct, the CIP, and Applicable Laws.

LabCorp will maintain the certificates required by this provision and make them available to HHS upon request.

- h. <u>Discipline</u>. LabCorp agrees to compile and maintain information on disciplinary actions taken against employees for violations of company policies related to the Applicable Laws. LabCorp will include a summary of such disciplinary actions in the Annual Report and will make the underlying information available to HHS upon request.
- i. Tests Not Performed and Composite Rate tests. LabCorp represents that it has implemented systems and manual processes to help prevent and eliminate billing for tests required to be billed as part of the Medicare End Stage Renal Disease (ESRD) composite rate and for tests not performed (due to reasons such as breakage, insufficient samples or other technical problems) as to all payers at all LabCorp facilities. LabCorp agrees to repay all Government programs for tests billed but not performed, as described in this paragraph, to the extent that such tests occur in spite of LabCorp's efforts to prevent and eliminate such billing.

Corporate Integrity Program Management

6. Compliance Officer and Compliance Committee The General Counsel of LabCorp serves as the Compliance Officer for the Company. The Compliance Officer has the ultimate oversight responsibility for LabCorp's compliance activities, including ensuring compliance with this Agreement, the LabCorp Business Practices Compliance Policy, and all Applicable Laws. The LabCorp Compliance Committee acts as a resource to assist the Compliance Officer in connection with the fulfillment of his duties. The Compliance Committee will meet on a regular basis to discuss, approve and oversee LabCorp compliance activities. As of the effective date of this Agreement, the Compliance Committee consists of the Compliance Officer, the heads of the Corporate Compliance Department, the Security Department, the Corporate Audit and Safety Department, and such representatives from the Finance, Human Resources, Information Systems, and Operations areas as may be designated from time to time by the President following consultation with the Compliance Officer. A list of the current Compliance Committee members is attached hereto as Exhibit 1. LabCorp agrees to update such list as necessary to reflect changes in the members of the Compliance Committee within a reasonable time of any such changes.

Department, headed by the Director of Corporate Compliance, is responsible for the day-to-day implementation, oversight, and enforcement of LabCorp's compliance policies and activities. As such, the Corporate Compliance Department is primarily responsible for developing and maintaining compliance policies, manuals, and training; establishing and maintaining systems for facilitating the internal reporting of suspected violations of the law and LabCorp policies; providing compliance counseling, investigations and audits; and providing regulatory, billing and reimbursement counseling and support. A description of the current Corporate Compliance Department Sections is attached as Exhibit 2. [This Exhibit will be the same Exhibit referenced below in the Paragraph entitled "Corporate Compliance Officers."]

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- 8. <u>Corporate Audit and Safety Department</u> The Vice President of Corporate Audit and Safety and his staff will provide audit and investigatory support in connection with this Agreement and LabCorp's compliance policies at the request of the Compliance Officer or the Director of Corporate Compliance.
- 9. <u>Director of Corporate Compliance</u> The Director of Corporate Compliance is head of the Corporate Compliance Department and is responsible for ensuring that the Corporate Compliance Department meets its responsibilities, as set forth above. The Director of Corporate Compliance reports to the General Counsel and Compliance Officer and the Corporate Compliance Officers report to the Director of Corporate Compliance.
- 10. <u>Corporate Compliance Officers</u> The Corporate Compliance Officers report to the Director of Corporate Compliance. Together, they are responsible for assisting the Compliance Officer, the Corporate Compliance Committee, and the Director of Corporate Compliance to ensure that LabCorp complies with this Agreement, LabCorp compliance policies and procedures, and all Applicable Laws. The current job descriptions and responsibilities of the Corporate Compliance Officers are attached as Exhibit 2. [This Exhibit will be the same Exhibit referenced above in the Paragraph entitled "Corporate Compliance Department."]
- 11. <u>Divisional Compliance Officers</u> The Divisional Compliance Officers act as liaisons between the various LabCorp divisions and functional areas and the Corporate Compliance Department. These Officers assist the Corporate Compliance Department to investigate and respond to, compliance questions and issues from their respective divisions. The Corporate Compliance Department is regularly informed of their

compliance activities and is consulted in connection with such activities. The Divisional Compliance Officers also assist the Corporate Compliance Department by providing the Department with reports as requested, by helping to investigate local compliance matters, and by ensuring that LabCorp's compliance policies and procedures are followed. The Divisional Compliance Officers are responsible for maintaining and distributing to their divisional employees LabCorp's compliance policies, procedures, manuals, and brochures, and for assisting the Corporate Compliance Department in connection with local training activities.

Standards of Conduct

12. The Corporate Compliance Department is responsible for developing, maintaining, updating as necessary, and distributing the Business Practices Compliance Policy and

the Code of Business Practices/Ethics Handbook, as well as any other manuals, handbooks, brochures, or booklets containing compliance guidelines and instructions. The Compliance Officer will consult with HCFA and the Medicare carriers at his discretion and as necessary when developing policies and procedures relating to the submission of Medicare claims. The standards of conduct set out in LabCorp's Business Practices Compliance Policy, the Code of Business Practices/Ethics Handbook and other manuals, handbooks, brochures and booklets, shall be maintained so as to ensure that LabCorp and each of its directors, officers, employees, and those individuals engaged directly by LabCorp as independent contractors involved in the sale, performance, or billing of lab services, maintain the business honesty and integrity required of a Medicare and Medicaid supplier, and that LabCorp's conduct is in strict compliance with Applicable Laws.

Annual Certifications

- 13. The Business Practices Compliance Policy ("Policy") and the Code of Business Practices/Ethics Handbook ("Handbook") will be circulated and/or made available to all LabCorp employees either via hard copy or, where available, computer transmission. Employees will be required to review the policies in the Policy and Handbook and to certify their review as set forth below:
- a. <u>Employees</u>: Continuing LabCorp's current policy, within 180 days of Execution of this Agreement, each person involved in the sale, marketing, or billing of laboratory services, and all phlebotomists, will (1) receive and review those policies applicable to each person's job performance, (2) discuss with his/her supervisor or the

supervisor's designee the Standards of Conduct set forth in the Policy and Handbook, and (3) sign an acknowledgment that he/she has complied with (1) and (2) above and will abide by those policies. Thereafter, within sixty (60) days of starting employment with LabCorp, new employees involved in the sale, marketing or billing of laboratory services, and all new phlebotomists, will also fulfill the requirements set forth in (1), (2), and (3) above. In years subsequent to the initial certification, each then-current employee involved in the sale, marketing or billing of laboratory services, and all phlebotomists, shall repeat the procedure of reviewing those policies in the Policy and Handbook applicable to that employee's job and sign a new acknowledgment. LabCorp will maintain the acknowledgments required by this provision and make them available to HHS upon request.

- b. Managers and Supervisors: Promotion of and adherence to this Agreement, the CIP and LabCorp Standards of Conduct shall be an element of the performance evaluation of each manager and supervisor. In addition to signing their own employee acknowledgments as required in subsection a., above, all managers and supervisors involved in the sale, marketing, or billing of laboratory services and all managers and supervisors who oversee phlebotomists also will attest that they or their designee has: (1) discussed with each employee under their supervision the content and application of the CIP and the Standards of Conduct found in the Policy and Handbook applicable to that employee's job; (2) informed each such employee that strict compliance with the Standards of Conduct and the CIP is a condition of employment; and (3) informed each such employee that LabCorp will take disciplinary action up to and including termination, for violation of the principles and practices set forth in the Standards of Conduct, as well as Applicable Laws. LabCorp will maintain the certificates required by this provision and make them available to HHS upon request.
- c. <u>Compliance Officer</u>: LabCorp shall submit, as part of each Annual Report to HHS pursuant to Paragraphs 22 and 23, a statement by the Compliance Officer that he has verified, based upon information and belief after due inquiry, (1) that the signed acknowledgments and certifications described above are being maintained, (2) that each employee involved in the sale, marketing, or billing of laboratory services, and each phlebotomist, has signed the acknowledgments as required by this provision and (3) that each manager and supervisor has signed the certifications as required by this provision.

Notice to Employees

14. LabCorp agrees to post in common work areas in its laboratory locations

a Notice (form of Notice attached as Exhibit 3) that details LabCorp's commitment to comply with all Applicable Laws in the conduct of its business. Such Notice will be placed in a prominent place accessible to employees.

HotLine

Agreement a "HotLine" telephone number for reporting suspected misconduct to the Corporate Compliance Department. LabCorp agrees to post a "HotLine" notice in common work areas in each of its laboratories identifying the telephone number to be used for such reporting. As part of the Annual Reports required by paragraphs 22 and 23, LabCorp shall provide a list of the number and type of all calls made to the "HotLine" during the previous year. With respect to any "HotLine" calls that allege possible violations of the Applicable Laws which may have a material impact on the Medicare and/or State health care programs, LabCorp shall include information on the nature of the allegations, a description of the action taken in response, the results of any internal investigation, and a description of any corrective action taken by LabCorp. Matters pending resolution at the time of the Annual Report period shall continue to be listed in the Annual Report until final resolution of the matter is reported.

Training and Education

- 16. LabCorp has instituted and will maintain an ongoing training and education program designed to ensure that each employee is aware of and understands the Applicable Laws, the CIP, the Standards of Conduct, and his or her duty to ensure compliance with the same. Upon the effective date of this Agreement, LabCorp agrees that such training and education will include notifying all LabCorp employees of the fact and substance of this Agreement and the importance of each employee's abiding by the terms of the Agreement, all Applicable Laws, and LabCorp policies and procedures. Such training and education will contain information on the potential consequences both to the employee and to LabCorp of any failure to achieve and maintain compliance with this Agreement, Applicable Laws, the CIP, and the Standards of Conduct set forth in the Policy and Handbook, including the range of disciplinary actions that may be taken in the event of such a failure.
- 17. Each person covered by the CIP shall receive at least one hour of initial training regarding the CIP. Thereafter, each employee shall receive not less than one (1) additional hour of training regarding the CIP annually. As part of this training, employees will be advised that compliance is a condition of their employment. A

schedule and subject outline for the training and education program shall be maintained by LabCorp and shall be open to inspection by HHS pursuant to the terms of Paragraph 34 regarding HHS rights.

Limitations on Hiring

LabCorp agrees that it shall not employ, contract with, or otherwise use 18. the services of any individual whom LabCorp knows or should have known, after reasonable inquiry, (a) has been convicted of a criminal offense related to health care. or (b) is currently listed by a federal agency as debarred, excluded, or otherwise ineligible for participation in federally funded health care programs. In furtherance of this requirement, LabCorp agrees to make reasonable inquiry as to any individual who is a prospective employee, agent, or individual considered for engagement directly by LabCorp as an independent contractor by reviewing the General Services Administration's List of Parties Excluded from Federal Programs and HHS/OIG Cumulative Sanction Report. LabCorp shall not be required to terminate the employment of individuals who are charged with a criminal offense related to health care, or proposed for debarment or exclusion during their employment with LabCorp, provided, however, that LabCorp will immediately remove such employees from direct responsibility for or involvement in any federally funded health care program until the resolution of such criminal charges or proposed debarment or exclusion. If the individual is subsequently convicted, debarred or excluded, LabCorp will terminate its employment relationship and/or affiliation with that individual. LabCorp shall notify HHS of each such personnel action taken, and the reasons therefor, within thirty (30) days of the action. For purposes of this Agreement, the term "convicted" shall have the meaning given in the Medicare Statute, 42 U.S.C. Section 1320a-7(i).

LabCorp Compliance Enforcement Activities

19. Compliance Activities. LabCorp will, on an on-going basis, engage in compliance enforcement activities, including conducting regular audits of its laboratories for compliance with Applicable Laws and LabCorp's policies as set forth in the Policy and Handbook and reviewing its billing policies, procedures and practices to ensure that federally funded health care programs are billed appropriately for services rendered. LabCorp shall include in the Annual Report required by paragraphs 22 and 23 a description of its efforts in this regard during the previous year and the results of those efforts.

20. Audits. As part of its regular compliance activities described in paragraph 19, LabCorp agrees, on an annual basis, to audit all of its geographic laboratory Divisions for compliance with at least four (4) of the policies contained in the Policy and Handbook, with such audits to include conducting random sample audits of laboratory facilities within the Divisions. In addition to these company-wide audits. LabCorp agrees that each year it will audit four (4) of its regional laboratory Divisions for compliance with at least four (4) other policies not covered in the company-wide audits. These "lab-specific audits" will be unannounced and will include an on-site visit and interviews with billing, sales, and other appropriate personnel. HHS may request that LabCorp include specific policies or issues in these audits, and LabCorp agrees to consider in good faith adding these issues or policies to the lab-specific audits. LabCorp will notify HHS of its decision on including these additional issues or policies in the lab-specific audits. LabCorp shall include in the Annual Report required by paragraphs 22 and 23 a description of its audit activities and the results thereof. LabCorp will make any supporting work papers and background information available to HHS upon request.

21. Duty to Investigate, Report and Correct.

- a. If, (1) in performing the compliance activities and audits described in paragraphs 19 and 20, above, or (2) LabCorp receives from any other source credible evidence of employee misconduct, LabCorp determines that there are reasonable grounds to suspect that a material violation of either (a) Applicable Laws, (b) this Agreement, or (c) LabCorp's Corporate Integrity Program has occurred, LabCorp will conduct an appropriate internal inquiry/investigation. The inquiry/investigation will be conducted using LabCorp's internal compliance staff, other employees, and such outside professionals as LabCorp deems necessary. LabCorp will make a determination of whether there are reasonable grounds to conclude that a material violation of the Applicable Laws governing federally funded health care programs occurred.
- b. If, at the conclusion of the internal inquiry/investigation, LabCorp identifies an overpayment amount owed to a federally funded health care program but determines there are no grounds to conclude that a material violation of Applicable Laws, this Agreement, or LabCorp's Standards of Conduct or policies contained in the Policy or Handbook occurred, LabCorp shall immediately undertake appropriate corrective actions to eliminate the cause of the overpayments and shall make prompt

restitution of the overpayment amount to the appropriate federally funded health care program pursuant to a process to be agreed upon by the HCFA Bureau of Program Operations. LabCorp also will report in the Annual Report: (1) the cause of the overpayment, (2) the calculation of the overpayment, (3) LabCorp's actions to correct the cause of the overpayment, and (4) any further steps LabCorp plans to take to address the cause of the overpayment and prevent it from recurring in the future.

- c. If, at the conclusion of the internal inquiry/investigation, LabCorp determines there are reasonable grounds to conclude that a material violation of Applicable Laws, this Agreement, or LabCorp's Standards of Conduct or policies contained in the Policy or Handbook did occur, LabCorp shall immediately undertake appropriate corrective actions, including prompt restitution of any overpayments to federally funded health care programs, pursuant to a process to be agreed upon by the HCFA Bureau of Program Operations, to the extent that LabCorp is legally responsible for any such overpayments. LabCorp also will report promptly to the addressee in the OIG Office of Enforcement and Compliance as required by paragraph 41: (1) its findings concerning the material violation, (2) the calculation of any overpayment, when necessary, (3) LabCorp's actions to correct such material violation, and (4) any further steps LabCorp plans to take to address such material violation and prevent it from recurring in the future.
- d. If LabCorp receives a final written report issued by an agency or organization charged with reviewing compliance with applicable licensure, accreditation, and/or certification requirements, which finds significant deficiencies relative to such requirements, LabCorp shall promptly take steps to correct such deficiencies to the reasonable satisfaction of the agency or organization, and will provide the OIG with a copy of the final written report issued by the agency or organization and a description of any corrective steps taken.
- e. The Annual Report shall include a list and summary description, for the preceding year, of (1) all internal inquiries/investigations conducted pursuant to paragraph 21.a., including any where LabCorp determined there were not reasonable grounds to believe that a material violation of Applicable Laws, this Agreement, or LabCorp's Corporate Integrity Program occurred, and (2) all reports made pursuant to paragraph 21.c.

Annual Reports

22. LabCorp will annually submit a report (the "Annual Report") to the OIG describing the measures taken by LabCorp to implement and to ensure compliance with this Agreement. The first such report shall be submitted no later than March 1, 1997. Such first Annual Report shall detail LabCorp's plans for complying with this Agreement. All subsequent Annual Reports shall be submitted no later than April 1 of the relevant year, beginning April 1, 1998 for the 1997 calendar year, and concluding with the last such report due April 1, 2002 for the calendar year 2001.

- 23. The Annual Report (other than the report due March 1, 1997) shall include, among other things, the following:
- a. A summary of the actions taken during the preceding twelve (12) months to comply with the terms of this Agreement, as well as Applicable Laws;
- b. A list of the documents, notices, instructions, and reports prepared by or for LabCorp during the preceding year to ensure compliance with this Agreement, as well as Applicable Laws;
- c. A narrative of the methods used and identification of the individuals involved in verifying compliance;
- d. The status of any ongoing governmental investigation of LabCorp involving possible violations of Applicable Laws;
- e. Verification that all applicable employees have signed the certification statement described in paragraph 13 and received the applicable compliance training described in paragraphs 16 and 17, and verification that marketing and sales personnel have completed the certifications described in paragraph 5.g.;
- f. Copies of the schedules and topic outlines for the training and education programs;
- g. Certification by the Compliance Officer, in accordance with 28 U.S.C. section 1746, that, to the best of his/her knowledge, LabCorp is in compliance with the terms of this Agreement, except as noted in accordance with subparagraph 23.h., below;
- h. A summary of the status and resolution of any internal investigation reported to the OIG pursuant to paragraph 21;

- i. Any substantive changes in the directives, instructions, or procedures for implementation of the Corporate Integrity Program;
- j. A list of the number and type of all calls made to the company Hot Line within the previous year, including the information required under paragraph 15;
- k. A list of all investigations of alleged violations or misconduct performed pursuant to paragraph 21 during the preceding year;
- 1. A summary of all disciplinary actions taken against employees for violations of LabCorp Standards of Conduct or policies contained in the Policy or Handbook and related to the Applicable Laws, as required by subparagraph 5.h.; and
- m. Any other documents or reports required by this Agreement and not specifically enumerated in this paragraph.
- 24. If, after receipt of the Annual Report, the OIG has reason to believe that compliance with this Agreement and Applicable Laws is not sufficiently evidenced by the Annual Report, either because (a) the OIG reasonably believes there is inadequate documentation of such compliance or (b) the OIG reasonably believes there is material non-compliance with the Agreement or Applicable Laws, the OIG shall notify LabCorp in writing of the reasons for its belief and LabCorp will be given the opportunity to conduct reasonable reviews and/or evaluations and to provide such additional information and documentation as may reasonably be required by the OIG to verify the representations in the Annual Report and compliance with the Agreement and with all Applicable Laws. In the event that the OIG reasonably determines that LabCorp is still not in material compliance after receipt of the additional information and documentation, the OIG, at its option, may, at LabCorp's expense: (1) conduct an audit and review, (2) retain independent professionals to conduct a third-party audit and review, or (3) require the LabCorp to retain independent professionals to audit and review where appropriate.

Other Reports to the OIG

25. In addition to the periodic written reports required herein, LabCorp shall notify the OIG within ten business days of the time LabCorp's Law Department receives notice of (a) the initiation of any criminal, civil or administrative investigation of LabCorp by any governmental entity, (b) receipt of subpoenas by LabCorp from any

state or federal governmental entity, (c) receipt of search warrants by LabCorp and/or searches carried out in any LabCorp facility, or (d) the disposition of legal action against LabCorp that reflects on LabCorp's ability to adequately provide services to Medicare and/or Medicaid beneficiaries, but only to the extent that any such investigation, subpoena, search warrant or search, or disposition of a legal action described herein in subparagraphs (a) through (d) involves the possible material violation of the Applicable Laws by LabCorp. LabCorp shall provide to the OIG as much information as is reasonably necessary to allow the OIG to determine the impact of the investigative or legal activity upon the present responsibility of LabCorp to continue as a Medicare and Medicaid supplier.

Diagnostic Information

- 26. The term "limited coverage policy" as used herein shall mean that the insurance carrier administering a federally funded health insurance program ("Carrier") or single State agency has decided to limit program coverage of certain clinical tests to situations where the tests were ordered and performed due to a set of pre-determined diagnoses. In regions where the Carrier or State have implemented a limited coverage policy for particular tests, LabCorp will submit to the Carrier or State diagnostic information obtained exclusively from the ordering physician, or the physician's authorized designee; provided, however, that nothing in this paragraph precludes LabCorp: (a) from contacting the ordering physician's office staff to obtain diagnostic information in the event that the physician has failed to provide such information to LabCorp; (b) from providing services pursuant to a standing order executed in connection with an extended course of treatment; or, (c) from accurately translating narrative diagnoses obtained from the physician to ICD-9 codes. LabCorp will document all such follow-up contacts and make such documentation available to the OIG upon request.
- 27. In implementing the provisions of paragraph 26, LabCorp will continue to train its employees regarding LabCorp's policies against using diagnostic information obtained from anyone other than the ordering physician or his/her legally authorized designee. However, as stated in paragraph 26 above, nothing in this Agreement precludes LabCorp from assigning diagnostic codes for tests performed pursuant to medically appropriate standing orders executed in connection with an extended course of treatment. Consistent with State law requirements, LabCorp will: (a) contact each nursing home where it relies upon standing orders executed in connection with an extended course of treatment to confirm in writing the continued

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validity of all current standing orders; and (b) will verify standing orders relied upon at draw stations with the physician, physician's office staff, or such other persons authorized by law. With respect to ESRD patients, at least once a year LabCorp will contact each ESRD facility or unit to request confirmation in writing of the continued validity of all current standing orders.

Sale of a Laboratory

- 28. In the event that LabCorp enters into a signed agreement, for example, a binding Letter of Intent, to sell or transfer ownership of any of its laboratories, LabCorp shall notify the OIG promptly after the execution of such agreement by all parties thereto.
- a. Upon closing any such sale or transfer of any of its laboratories, LabCorp shall refrain from the use of all Medicare and Medicaid provider numbers assigned to any laboratory sold or transferred except in compliance with Medicare and Medicaid program requirements.
- b. No later than thirty (30) days prior to the scheduled closing for the sale or transfer of any laboratory, LabCorp will transmit to the OIG: (1) the cumulative information already gathered at that time by LabCorp with respect to such laboratory that otherwise LabCorp would be required to include in its next Annual Report; (2) a listing of all provider numbers under which services performed by that laboratory were billed to the Medicare and/or Medicaid programs, together with a statement regarding the anticipated post-closing use of such numbers; and (3) a listing of corrective compliance actions undertaken by LabCorp with respect to that facility and previously reported pursuant to this Agreement. In the event that the scheduled Closing is within 45 days of the date of the most recent Annual Report, no report pursuant to this subsection b. shall be required.

Closing and Name Changes

29. A LabCorp laboratory will be closed within the meaning of this paragraph when it ceases using both the LabCorp requisition form and any provider number presently used by LabCorp. The closing of a LabCorp laboratory shall exclude a sale or transfer within the meaning of paragraph 28. LabCorp will notify the OIG at least thirty (30) days in advance of such closing and will both disclose all provider numbers used by that laboratory and advise the OIG regarding any plans to use those provider numbers in the future. In the event that all LabCorp laboratories are closed as

defined in this paragraph, this Agreement will be suspended and cease to have any force and effect at such time as LabCorp ceases all use of any and all provider numbers presently used by it. In the event that LabCorp reopens any or all laboratories, this Agreement will be reactivated and remain in force and effect through the end of the Term of this Agreement.

30. In the event that a LabCorp laboratory undergoes a name change, for business or internal organizational reasons, but is not closed as defined in paragraph 29 above, LabCorp will notify the OIG in advance of such name change, and all provisions of this Agreement will remain in force and effect, except that such name change will not constitute a sale or transfer within the meaning of paragraph 28.

Applicability to New Labs

31. LabCorp will advise the OIG of any purchase by LabCorp of a new clinical laboratory or a company which owns any clinical laboratories within thirty (30) days of the closing of such transaction. In the event that LabCorp purchases a new clinical laboratory or a company which owns any clinical laboratories, LabCorp shall implement all applicable provisions of this Agreement, including any training or education requirements, within 180 days following such purchase or by such later date as agreed to by the OIG, such agreement not to be unreasonably withheld.

Retention of Records

- 32. LabCorp will maintain any reports and certifications specifically required by this Agreement for a period of six (6) years from creation of those reports and certifications. LabCorp will maintain all other documentation specifically required by this Agreement, either in original, electronic, microfilm or microfiche-type form, for a period of six (6) years from its creation, and upon request will provide copies to the OIG within a reasonable period of time.
- 33. LabCorp shall maintain written reports and minutes of any and all LabCorp Board meetings reflecting the reports made to the LabCorp Board by the Compliance Officer, the Chief Executive Officer of LabCorp, or any other Compliance Committee member, and the LabCorp Board's decisions or directions concerning matters related to the CIP or this Agreement, and upon request will provide to the OIG within a reasonable period of time copies of those portions of such reports or minutes that concern matters related to compliance with Applicable Laws, the CIP, or this Agreement.

OIG Right to Inspect

34. In addition to any other right the OIG may have by statute, regulation, or contract, upon reasonable notice, the OIG or any duly authorized representatives may examine at LabCorp's place of business LabCorp's books, records, and other company documents and supporting materials for the purpose of verifying and evaluating LabCorp's compliance with the terms of this Agreement and Applicable Laws. The OIG also shall be entitled upon reasonable notice to inspect all records required to be generated and maintained as part of this Agreement, and the OIG shall be allowed to copy such documents and retain any such copies or request, receive and retain copies of such documents from LabCorp. The materials described above shall be made available by LabCorp at all reasonable times for inspection, audit, or reproduction. Further, for purposes of this provision, upon reasonable notice, the OIG or any duly authorized representatives may interview any LabCorp employee who consents to be interviewed at the employee's place of business during normal business hours or at such other place and time as may be mutually agreed between the employee and the OIG. Each employee shall be advised by the OIG or any duly authorized representative prior to any such interview that the employee may elect to be interviewed with or without a representative of LabCorp present. The decision of any employee not to be interviewed by any government representative shall not be deemed a breach of this Agreement.

Notice to HHS Regarding Corporate Compliance Officers

35. Attached to this Agreement as Exhibit 1 is a list of LabCorp's Compliance Committee Members. Within thirty (30) days of the Execution Date of this Agreement, LabCorp will submit a list of any other members of LabCorp's Management responsible for compliance coordination, including the identities of the Divisional Compliance Officers. LabCorp agrees to update such list(s) as necessary and within a reasonable period of time to reflect changes in position or identity of management personnel responsible for compliance.

Notice to the OIG Regarding Corporate Executive Officers

36. Within thirty (30) days of the Execution Date of this Agreement, LabCorp will submit a list of its corporate executive officers and directors to the OIG. LabCorp will notify the OIG of any changes in the position or identity of its corporate executive officers and directors within a reasonable time.

Material Breach: Notice and Opportunity to Cure

37. In the event that the OIG believes that LabCorp is in material breach of one or more of its obligations under this Agreement, the OIG shall give LabCorp written notice by certified mail specifying the nature and extent of the alleged breach. LabCorp will have thirty (30) days from receipt of the notice to: (a) fully cure the breach; or (b) otherwise satisfy the OIG that (1) it is in compliance with the Agreement or (2) the breach cannot be reasonably cured within thirty (30) days, but that LabCorp has commenced action to cure the breach and is pursuing such action with diligence.

Exclusion or Suspension from Programs

- 38. If, notwithstanding LabCorp's efforts to cure or otherwise satisfy the OIG pursuant to paragraph 37, the OIG continues to believe that LabCorp is in material breach of any provision of the Agreement, the OIG may, through its Office of Counsel to the Inspector General, declare LabCorp to be in default of this Agreement and may seek to exclude or suspend LabCorp from participation in the Title XVIII (Medicare) program, Title XIX (Medicaid) program, and other state health care programs, as defined in 42 U.S.C. section 1320a-7(h), until such time as LabCorp has fully cured such material breach or otherwise satisfied the OIG in accordance with paragraph 37 above. In the event that LabCorp fully cures the material breach or otherwise satisfies the OIG, it will be promptly reinstated, retroactive to the date of cure.
- 39. An exclusion pursuant to paragraph 38 of this Agreement shall be deemed an exclusion pursuant to 42 U.S.C. Section 1320a-7(b)(7). Upon notification by the OIG of its intent to exclude or suspend LabCorp from participation, LabCorp is entitled to pre-exclusion due process as afforded a provider under 42 U.S.C. Section 1320a-7(f), including judicial review pursuant to 42 U.S.C. Sections 405(g) and 1320a-7(f), or other applicable statute. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion or suspension based on the material breach of this Agreement shall be: (a) whether LabCorp was in material breach of one or more of its obligations under this Agreement at the time of and as specified in the notice given to LabCorp; (b) whether such material breach was continuing on the date on which the OIG notified LabCorp of its proposal to exclude; and (c) whether LabCorp failed to cure the material breach or otherwise satisfy the OIG within thirty (30) days after receiving notice thereof from the OIG. The OIG shall bear the burden of proof in such proceedings.
 - 40. Subsequent to a final decision to exclude or suspend LabCorp, LabCorp

retains the right to apply for reinstatement under 42 C.F.R. sections 1001.3001-1001.3004. The parties further agree that the procedures governing administrative review of OIG's determination to seek exclusion or suspension, as set forth by 42 C.F.R. Parts 1001 and 1005, are applicable, except that OIG shall bear the burden of proof in such proceedings.

Notices Required Hereunder

41. Any notices or information required hereunder shall be in writing and delivered or mailed by registered or certified mail, postage prepaid, as follows:

If to LabCorp, to: Bradford T. Smith, Esq.

General Counsel, Executive Vice President and Compliance Officer

Laboratory Corporation of America Holdings

358 S. Main Street

Burlington, North Carolina, 27215

cc: David M. Ledbetter, Esq.

Associate Vice President, Director of

Corporate Compliance

Laboratory Corporation of America Holdings

358 S. Main Street

Burlington, North Carolina, 27215

If to HHS, to: Eileen T. Boyd, Esq.

Deputy Inspector General

Office of Enforcement and Compliance

Office of Inspector General

Department of Health and Human Services 330 Independence Ave. SW, Room 5600

Washington, D.C. 20201

If to HCFA, to: Linda Ruiz, Director

Office of Benefits Integrity

Mail Stop S3-02-26

7500 Security Boulevard Baltimore, Maryland 21207

Costs

42. LabCorp agrees that all costs, as defined in FAR 31.205-47, incurred on behalf of LabCorp's current or former officers or directors arising from, related to, or in connection with the Government's civil and criminal investigations, LabCorp's defense and settlement thereof, the Civil Settlement Agreement entered into by LabCorp and the United States, or the performance or administration of this Agreement, shall be unallowable for Medicare, Medicaid, or other Government contract accounting purposes. LabCorp agrees to account separately for such costs. LabCorp shall treat these costs as unallowable costs for Government contract accounting purposes and shall account separately for such costs. Included in these unallowable costs are any legal or related costs expended on behalf of any convicted LabCorp employee. LabCorp also agrees to treat as unallowable the full salary and benefits costs of any officer, employee, or consultant removed from government contracting in accordance with the LabCorp policy regarding employees who are indicted, debarred, suspended, or proposed for debarment, and the cost of any severance payments or early retirement incentive payments paid to employees released from the company as a result of the wrongdoing at issue here.

Privileges Maintained

43. LabCorp contends that the attorney-client privilege and the attorney workproduct doctrine may attach to certain information, documents, communications, notes, memoranda, recordings, or detailed descriptions of interviews, or other information related to the subject matter of this Agreement. LabCorp presently intends to preserve this privilege and doctrine to the extent permitted by law, and the OIG recognizes that LabCorp may assert them, to the extent they may exist. Nothing in this Agreement shall be construed to require the production of material protected by such privilege and/or doctrine, except that LabCorp agrees that it shall not assert the privilege and/or doctrine as a basis for withholding any audits, audit work papers, supporting exhibits or analytical documents supporting such audit, with respect to any audit performed pursuant to this Agreement to determine the overpayment from or cost impact to federally funded health care programs of LabCorp billings. The OIG reserves the right to contest the asserted applicability of the privilege and/or doctrine in any given instance. Nothing in the Agreement, including the submission of reports, documents or other information pursuant to this Agreement, is intended as, constitutes, or shall be construed as a waiver of LabCorp's attorney-client, work-product, or other privileges and rights, including rights it may have under the Freedom of Information Act. The OIG specifically agrees that it will not contend that LabCorp's production of any

reports or their underlying documents, or the furnishing of additional information relating to this Agreement, constitutes a waiver of the attorney-client privilege and work-product doctrine as may be applicable.

Confidentiality

- 44. The confidentiality of all documents and other information provided by LabCorp in connection with its obligations under this Agreement shall be maintained by the OIG except to the extent disclosure is required by law. Nothing in this Agreement shall be construed to prohibit the OIG from providing information to any other department or agency of the United States Government or of any State charged with enforcing the laws against health care fraud if the information relates to matters within the department's or agency's jurisdiction, provided that any such entity receiving such information shall be advised by the OIG of the confidentiality provisions of this Agreement. The OIG agrees that certain information submitted to it under this Agreement may constitute trade secrets or confidential commercial or financial information within the meaning of section 552(b) of the Freedom of Information Act ("FOIA"), 5 U.S.C. Section 552(b)(4). Since the OIG has determined that such records may fall under this exemption, the OIG further agrees to follow its predisclosure notification procedures set out in 45 C.F.R. Section 5.65. These procedures include prior notice to LabCorp of any potential release of records under the FOIA and an opportunity to provide information as to why the information is exempt under 5 U.S.C. Section 552(b)(4). LabCorp will also be given advance notice if the OIG decides that any such information is not exempt under section 552(b)(4).
- 45. This Agreement does not constitute, and shall not be construed as, an admission by any person or entity, with respect to any issue of law or fact. The performance under this Agreement of any of the obligations of LabCorp, including the submission of documents and reports required by this Agreement, does not constitute, and shall not be construed as, an admission by any person or entity, with respect to any issue of law or fact.

Modifications

46. This Agreement may not be changed, altered or modified, except in writing signed by all parties.

Definitions

- 47. For purposes of this Agreement, the following definitions will apply:
- a. <u>General Requisition Form.</u> A general requisition form is one which presents the noncustomized test offerings of the laboratory.
- b. <u>Customized Profile</u>. A customized profile is a selection of tests grouped together at the request of the referring physician and which can be ordered as a group, rather than separately.
- c. Applicable Laws. Title XVIII of the Social Security Act, 42 U.S.C. Sections 1395-1395ccc (the Medicare statute); Title XIX of the Social Security Act, 42 U.S.C. Sections 1396 et seq. (the Medicaid statute); the Medicare Anti-Kickback Statute, 42 U.S.C. Section 1320a-7b(b); the False Claims Act, 31 U.S.C. Sections 3729 et seq. (as amended); the Program Fraud Civil Remedies Act, 31 U.S.C. Sections 3801 et seq.; the federal Anti-Kickback Act, 42 U.S.C. Sections 52 et seq.; and the Civil Monetary Penalties Law, 42 U.S.C. Sections 1320a-7a and 1320a-7b; and all applicable implementing regulations.
- d. <u>Material Violation</u>. A material violation is one which: (1) has, or has the potential to have, a significant, adverse financial impact on the Medicare and/or Medicaid programs; (2) is a systemic failure to comply with Applicable Laws, the CIP, this Agreement, the Standards of Conduct, or the policies or procedures contained in the Policy or Handbook, regardless of financial impact on the Medicare and/or Medicaid programs; or (3) has a significant adverse effect on the quality of care provided to program beneficiaries.
- e. <u>Material Breach</u>. A material breach means a failure to abide by a significant term of this Agreement.
- f. <u>Convicted.</u> The term "convicted" shall have the meaning given in the Medicare Statute, 42 U.S.C. Section 1320a-7(i): "... an individual or entity is considered to have been 'convicted' of a criminal offense -- (1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged; (2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court; (3) when a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court; or (4) when the individual or entity has entered into participation in a first offender, deferred adjudication, or other

arrangement or program where judgment of conviction has been withheld."

g. Annual Report. The Annual Report is a yearly report describing the LabCorp compliance activities conducted during the previous calendar year and the findings resulting from those activities. The Annual Report contains all of the summaries, descriptions, reports, and supporting documentation (where appropriate) required of LabCorp by this Agreement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Dated: 11/20/96	By: / Mary
	Lewis Morris
	Assistant Inspector General
	for Legal Affairs
	Office of Inspector General
	United States Department of
	Health and Human Services
LABORATORY CORPORATION OF AMERICA HOLDINGS	
Dated:	By:
	Bradford T. Smith, Esq.
	General Counsel, Executive Vice
	President and Compliance Officer
	Laboratory Corporation of America Holdings
	358 S. Main Street
	Burlington, North Carolina, 27215
Dated:	By: James B. Powell, M.D.
	President and Chief Executive Officer
	Laboratory Corporation of America
	Holdings
	358 S. Main Street
	Burlington, North Carolina, 27215